5.6 Verification and Validation

5.6.1 *Verification*

[1] The RM shall conduct and document a verification review for new and revised technical procedures. Documented reviews shall be retained in the DHF. The following items should be considered, as a minimum:

- Operational Safety Analysis (OSA)/Operational Safety Requirements (OSR)/TSR/OSHA applicability
- Ability to complete the task as written
- Accurate directions for form completion
- Complete, correct, and available references
- Complete and accurate DHF package

A verification checklist in Appendix 9, of the SDRM may be used for verification review documentation.

J. Hoez. 03/12/99

5.6.2 *Validation*

[1] For new or revised technical procedures, the RM shall conduct and document a validation review prior-to-approval. The RM assigns a validator to perform a simulated or actual walkdown of the document to determine whether the document can be correctly, safely, and effectively performed. A Validation Checklist (identified in Appendix 8, of the SDRM) may be used for documenting the review. The documented review shall be maintained in the DHF.

J. Hoez. 03/12/99

5.7 Screening/Safety Reviews

isi 03/20/97

[1] For all new or revised technical procedures, the RM shall obtain an SES/USQD process review in accordance with 1-C10-NSM-04.03, Safety Evaluation Screen, and 1-C11-NSM-04.05, Unreviewed Safety Question Determination. Technical procedures may be exempted from the SES/USQD process if they meet the requirements of 1-C10-NSM-04.03, Appendix 1, Categorical Exclusion from the SES/USQD Review Process. Documented evidence of screening activities or exemption determination shall be retained in the DHF

isi 03/20/97

[2] The RM shall initiate an Independent Safety Review (ISR) (formerly known as Operations Review Committee [ORC] review) for all new or revised technical procedures. ISRs shall be performed in accordance with 1-52000-ADM-02.01, Operations Review Requirements. Documented evidence of ISRs will be retained in the DHF

5.8 Supplemental Review

isi 03/20/97

[1] The RM should consider having documents extensively revised as a result of internal or external reviews, V&V reviews, safety screens, or ISRs resubmitted for review and comment.

[2] Prior to issue, the RM will consider the document for classification in accordance with the Site Security Manual.

5.8 Approval

[1] After resolution of comments, appropriate concurrence, and any required safety review comment resolution, the RM shall obtain a review for classification, as required, and approve the document. Approval authority for documents is depicted in Table 1. Approval documentation, including correspondence, shall be retained in the DHF.

[2] Documents become effective on the date indicated on the first page. The RM and organization managers should agree on the effective date to allow for necessary training prior to the effective date.

5.9 Training/Issuance/Document History File

[1] Training for effective implementation of RMRS documents will be considered on a case-by-case basis by the RM and other managers affected by the document. Where base competency requires training, it should be coordinated with the RMRS training organization. The RM is shall participate in defining training, certification, and qualification requirements for the document generated.

[2] After approval of the document, the RM shall assemble the master document and DHF (ref.: Section 3 definition), and formally transmit the package to RMRS Document Control.

[3] With the exception of Job-Aids, all active documents must have a controlled distribution.
[4] Controlled distributions will be facilitated by RMRS Document Control using transmittal receipt acknowledgment forms. Controlled distribution should be extended to the Site Standards Management organization.
[5] RMRS Document Control will retain the master document and DHF in a one-hour fire rated cabinet.

5.10 Changes, Revisions, Periodic Reviews, and Cancellation

03/20/97

[1] Changes to documents are facilitated by the RM. Changes differ from revisions in that changes doe not require re-issue of the document, and may be handwritten, typed or word processed. The RM makes changes by obtaining the electronic copy from Document Control, and editing the document to reflect the change. A vertical change bar is placed to the left of the change in the document margin, and the date is placed vertically outside of the revision bar. No other changes to the page or header is required.
[2] The RM determines if review of the change is required, and obtains needed review(s) prior to submitting the change to Document Control for controlled distribution. Review and comment disposition related to document changes, including field changes, will be documented.
[3] The RM transmits the change to RMRS Document Control for controlled distribution of the change.
[4] The RM should initiate a document revision when changes have made the document difficult to perform, or when the process being controlled by the document has changed.

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[5] The RM begins the revision by initiating a Controlled Document Checklist, obtaining the electronic version from Document Control, making revisions as necessary, and following the process defined from Section 5.4 through 5.9. Revisions require the same level of review as the original issue.
[6] The RM should initiate a periodic review to ensure that the document accurately and adequately satisfies current technical and administrative requirements and guidelines. Frequency should be based on the following schedule:

- 1 year -- Emergency Preparedness procedures
- 3 years -- Procedures that potentially affect vital safety systems
- 4 years -- all other documents

[7] The RM initiates cancellation of documents by formally notifying RMRS Document Control. Document Control facilitates cancellation through transmittal receipt form, and retains the canceled document and DHF in accordance with records management requirements.

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[8] For *field changes*, the RM determines if review of the change is required (see para. 5.4.1[2], and 5.7) and obtains needed review(s) and concurrence prior to implementation in the field. Field changes will be transmitted to RMRS Document Control for controlled distribution within 48 hours, beginning the next scheduled work day after the change was made.

6. RECORDS

The following documents are initiated, processed or maintained as a result of this procedure and shall be processed as follows:

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Record Identification	Record Type Determination	Protection / Storage Methods	Processing Instructions
Documents related to **WIPP/LL/LLM** : • Document History File (DHF) including the following as needed: a) completed review comment resolution documentation; b) draft document submitted for review; c) justification for revision; d) verification and validation;	*In-Process WIPP/LL/LLM Quality Assurance Record*	Manager shall implement a reasonable level of protection to prevent loss and/or degradation. Documents shall be protected utilizing standard office equipment and methods when not in use.	Continue prescribed processing of document(s) Once approved by the responsible manager, transmit the document and DHF to RMRS Document Control Center in accordance with DC-06.01.

e) electronic copy of approved document; e) RMRS Controlled Document checklist			

Documents **NOT** related to WIPP/LL/LLM : Document History File (DHF) including the following as needed: a) completed review comment resolution documentation; b) draft document submitted for review; c) justification for revision; d) verification and validation; e) electronic copy of approved document; e) RMRS Controlled Document checklist	*Quality Assurance Record*	Manager shall implement a reasonable level of protection to prevent loss and/or degradation while in process. Documents shall be protected utilizing standard office equipment and methods while in process.	Continue prescribed processing of document(s) Once approved by the responsible manager, transmit the document and DHF to RMRS Document Control Center in accordance with DC-06.01.

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7. REFERENCES

7.1 RMRS-QAPD-001, RMRS, Quality Assurance Program Description

7.2 1-P04-CMCAP-16.00, Commitments Management and Corrective Action Process

7.3 1-V41-RM-001, Records Management Guidance for Records Sources

7.4 1-52000-ADM-02.01, Operations Review Requirements

7.5 1-31000-COOP-010, Control of Operator Aids

7.6 1-C10-NSM-04.03, Safety Evaluation Screen

7.7 1-C11-NSM-04.05, Unreviewed Safety Question Determination

7.8 RFETS Site Quality Assurance Manual

7.9 Site Security Manual

7.10 PROCEDURE DC-06.01, RMRS Document Control Program

7.11 DOE Order 5700.6C, Quality Assurance

7.12 10 CFR 830.120, Quality Assurance Requirements

7.13 1-77000-DC-001, Document Control Program

7.14 2-G18-ER-ADM-17.01, Records Capture and Transmittal

7.15 2-N96-ER-ADM-17.09, Records Identification, Preliminary Preparation, and Creation

APPENDIX 1
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DOCUMENT DEVELOPMENT AND CONTROL PROCESS FLOW DIAGRAM